IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re Application of:

Sundaram VENKATRAMAN et al. Art Unit: 1625

Application No.: 10/786,556 Examiner: P. L. Morris

Filed: February 25, 2004

For: CRYSTALLINE FORM Z OF RABEPRAZOLE SODIUM AND PROCESS FOR PREPARATION THEREOF

Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

Sir:

BRIEF ON APPEAL

Further to the Notice of Appeal filed on September 8, 2006 for the subject application, a brief in support of the appeal is now submitted. Submission of a brief in support of the appeal is due by November 8, 2006. Accordingly, this brief is being timely filed.

1. Real Party in Interest

The real parties in interest are Dr. Reddy's Laboratories Limited and Dr. Reddy's Laboratories, Inc., assignees of the application from the inventors/appellants.

2. Related Appeals and Interferences

There are no appeals or interferences that are related to this appeal, or which will affect or have a bearing on this appeal.

3. Status of the Claims

Claims 1-3, 5-9, 26 and 27 were finally rejected in an Office Action mailed on May 10, 2006. Claims 4 and 10 have been cancelled. Claims 11-25 have been withdrawn from consideration. Accordingly, claims 1-3, 5-9, 26 and 27 are the subject of this appeal.

4. Status of Amendments

An amendment was filed on August 7, 2006, subsequent to the final rejection. Claims 1 and 6-9 were amended, and claims 11-25 were cancelled. The Examiner indicated in an Advisory Action mailed on August 11, 2006, that the proposed amendments would not be entered for purposes of appeal because they raised new issues that would require further consideration and/or search and they did not place the application in better form for appeal. Specifically, the Examiner stated that the amendment to claim 6 would require a new § 112 rejection because the expression "form Z ... sodium" was indefinite. The Examiner further stated that the Appellants failed to provide any objective evidence establishing any unobvious or unexpected properties for the claimed compound.

5. Summary of Claimed Subject Matter

The claimed subject matter encompasses polymorphic crystalline form Z of the known drug compound rabeprazole sodium.

Independent claim 1 is directed to crystalline Form Z of rabeprazole sodium having substantially the same X-ray powder diffraction pattern as shown in Figure 1. (Instant specification, page 9, line 12 to page 11, line 16.)

Independent claim 6 is directed to solid rabeprazole sodium wherein at least 80% by weight is crystalline Form Z of rabeprazole sodium having substantially the same X-ray powder diffraction pattern as shown in Figure 1. (Instant specification, page 12, lines 1-3.)

The dependent claims are directed to various embodiments of the disclosed compound.

A copy of the appealed claims is appended hereto, beginning on page 16.

6. Grounds of Rejection to be Reviewed on Appeal

A. Whether claims 1-3, 5-9, 26 and 27 are anticipated under 35 U.S.C. §§ 102(a), (b) and/or (e) by Takashi et al. (JP 2001-39975; "Takashi"), Souda et al. (U.S. Patent No. 5,045,552; "Souda") and Reddy et al. (WO 03/082858; "Reddy").

B. Whether claims 1-3, 5-9, 26 and 27 are unpatentable under 35 U.S.C. § 103(a) over the combined teachings of Takashi, Souda and Nochi et al. (*Chem. Pharm. Bull.* 44(10) 1853-1857 (1996); "Nochi") in view of Brittain, ("Polymorphism in Pharmaceutical Solids," 1999, pp. 228-361; "Brittain"), Haleblian et al. (*J. Pharm. Sciences*, (1969), 58 pp. 911-929; "Haleblian"), Muzaffar et al. (*J. of Pharmacy* (Lahore) 1979, 1(1), 59-66; "Muzaffer"), Jain et al. (*Indian Drugs*, 1986, 23 (6) 315-329; "Jain"), Chemical & Engineering News, Feb. 2003 ("C&E News"), U.S. Pharmacopia, 1995, pp. 1843-1844 ("USP") and Concise Encyclopedia Chemistry, pages 872-873 (1993) ("CEC").

C. Whether claims 1-3, 5-9, 26 and 27 are invalid under 35 U.S.C. § 112, first paragraph, for lacking written description and enablement regarding whether the compound and compositions are able to maintain the crystalline form claimed.

D. Whether claims 1 and 6-9 are indefinite under 35 U.S.C. § 112, first paragraph, for reciting the term "rabeprazole."

E. Whether claims 1-3, 5-9, 26 and 27 are unpatentable under the judicially created doctrine of obviousness-type double patenting over claims 1-13, 26 and 27 of copending U.S. Patent Application No. 10/505,826 in view of Haleblian, Muzaffar, Jain, C&E News, USP, Brittain and CEC.

7. Argument

A. Rejection of Claims 1-3, 5-9, 26 and 27 Under 35 U.S.C. §§ 102(a), (b) and/or (e)

Claims 1-3, 5-9, 26 and 27 stand finally rejected under 35 U.S.C. §§ 102(a), (b) and/or (e) as allegedly anticipated by Takashi, Souda and Reddy. According to the Examiner, Takashi, Souda and Reddy specifically disclose the instant rabeprazole sodium salt. Particular attention is drawn by Examiner to Example 33 of Souda and the compound of formula 1 of Reddy. The Examiner states that the term "Form Z" does not offer any demarcation of the product from the prior art crystalline product.

It has long been the law that anticipation can properly be held only where a prior art document teaches each and every limitation of the rejected claim. *See Verdegaal Bros. v. Union Oil Co. of Cal.*, 814 F.2d 628, 631 (Fed. Cir. 1987). Contrary to the Examiner's position, Takashi, Souda and Reddy do not disclose the instant rabeprazole sodium salt with all its limitations. Claims 1-3, 5-9, 26 and 27 are directed to crystalline Form Z having substantially the same X-ray powder diffraction pattern as shown in Figure 1 of the instant specification, a pattern which is not expressly or inherently disclosed in the references cited by the Examiner.

Takashi appears to describe a crystal of rabeprazole salt acetone complex having an X-ray diffraction pattern at page 5 substantially different from that shown in Figure 1 of the instant specification. Souda describes in Example 33 a process for making rabeprazole sodium salt. There is no teaching or suggestion in Souda of crystalline rabeprazole sodium polymorphs, let alone the particular crystalline Form Z disclosed and claimed in the instant specification. Reddy discloses Forms X and Y of rabeprazole sodium, each having X-ray diffraction patterns substantially different from that shown in Figure 1 of the instant specification.

Appellants submit that by incorporating the X-ray diffraction as shown in Figure 1 of the instant specification, the claims adequately distinguish the instant crystalline Form Z of rabeprazole sodium from the materials disclosed in the cited

references. As such, Takashi, Souda and Reddy cannot anticipate claims 1-3, 5-9, 26 and 27 under §§ 102(a), (b) and/or (e), and the rejection should not be sustained. *See Ex parte Havens*, Appeal No. 2001-0987 of Application No. 08/732,254, now US 6,452,007 B1 (BPAI 2001) ("The examiner has provided no evidence or scientific reasoning to show that the delavirdine mesylate disclosed and claimed [in the prior art reference] is in the [claimed] crystal form. Therefore, the examiner has not made out a prima facie case of anticipation by inherency.").

In support of the § 102 rejection, the Examiner stated at page 3 of the Final Office Action mailed May 10, 2006 ("Final Office Action"):

> [I]n the strictest sense, polymorphs are different crystalline forms of the **same pure substance** in which the molecules have different arrangements and/or different confirmations of the molecules. (Emphasis in original.)

In doing so, the Examiner appears to be taking the position that new polymorphs are not patentable *per se* over the originally identified compound or previously identified polymorphs of the same compound. But this is inconsistent with current patent law and practice. The USPTO routinely issues patents directed to new solid state forms over other forms of the same compound. Some recently issued patents include, *e.g.*, U.S. Patent Nos. 6,958,337, 6,906,087, 6,894,171, 6,884,805 and 6,858,631. Furthermore, the Federal Circuit and the CCPA have consistently held new solid state forms to be patentable over other forms of the same compound, thereby fulfilling the novelty requirement. *See, e.g.*, *Glaxo Inc. v. Novopharm Ltd.*, 52 F.3d 1043 (Fed. Cir. 1995) (ranitidine form 2 novel over form 1); *Bristol-Myers Co. v. U.S. Int'l Trade Comm'n*, 892 F.2d 1050, (Fed. Cir. Dec. 8, 1989) (unpublished decision) (Bouzard cefadroxil monohydrate novel and unobvious over other cefadroxil forms); *Silvestri v. Grant*, 496 F.2d 593 (CCPA 1974) (ampicillin B patentably distinct from ampicillin A); *In re Irani*, 427 F.2d 806 (CCPA 1970) (crystalline anhydrous ATMP novel and unobvious over amorphous ATMP); *In re Cofer*, 354 F.2d 664 (CCPA 1966) (crystalline 2,2-B compound novel and unobvious over liquid 2,2-B).

Indeed, the Examiner recognized the novelty of the crystalline Form Z of rabeprazole sodium disclosed and claimed in the instant application. In

describing the "nature of the invention" for an enablement rejection at page 9 of the Final Office Action (discussed *infra*), the Examiner stated:

> The nature of the invention is the preparation of a novel crystalline forms Z of rabeprazole sodium and compositions. (Emphasis added.)

Accordingly, Appellants submit that claims 1-3, 5-9, 26 and 27 are not *per se* unpatentable under § 102, and the rejection should not be sustained.

B. Rejection of Claims 1-3, 5-9, 26 and 27 Under 35 U.S.C. § 103(a)

Claims 1-3, 5-9, 26 and 27 stand finally rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over the combined teachings of Takashi, Souda and Nochi in view of Brittain, Haleblian, Muzaffar, Jain, C&E News, USP and CEC. According to the Examiner, Takashi, Souda and Nochi teach the crystalline form of rabeprazole and rabeprazole sodium as well as pharmaceutical compositions. Brittain, Haleblian, Muzaffar and Jain are said to teach that compounds can exist in different crystalline forms, while C&E News, USP and CEC are said to teach that at any particular temperature and pressure, only one crystalline form is thermodynamically stable. Thus, according to the Examiner, it would appear obvious to one skilled in the art that the instant compound would exist in different polymorphic forms. No unexpected or unobvious properties were noted by the Examiner.

The standards for making an obviousness rejection are summarized in MPEP § 706.02(j) as follows:

> To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art and not based on

> applicant's disclosure. *In re Vaeck,* 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

As discussed above with respect to the § 102 rejection, there is no teaching or suggestion in Takashi or Souda of the instantly claimed crystalline Form Z of rabeprazole sodium. Nochi describes at page 1853 X-ray crystallographic analyses of a synthetic intermediate of rabeprazole sodium (benzyloxymethylated rabeprazole sodium). Nochi explains in the Experimental Section that rabeprazole sodium was prepared according to the method described in Souda, but that "E3810 (rabeprazole sodium) could hardly be crystallized," casting doubt on the likelihood that Souda discloses a crystalline rabeprazole sodium. Thus, none of the references, alone or in combination, teach or suggest crystalline Form Z of rabeprazole sodium having substantially the same X-ray powder diffraction pattern as shown in Figure 1 of the instant specification. This alone is enough to overcome the Examiner's obviousness rejection. *See Ex parte Havens*, *supra* ("The examiner's obviousness rejection seems to suffer the same infirmity as her anticipation rejection . . . The examiner has provided no evidence or convincing reason why the prior art disclosure of delavirdine mesylate in an undefined state would have suggested the specific S and T crystal forms that are the subject of the instant claims.") (emphasis added). The ancillary references cited by the Examiner merely provide general background information relating to the study and preparation of polymorphs or case histories of specific polymorphic compounds (none of which is rabeprazole sodium), and thus add nothing over the primary references.

Contrary to the Examiner's position, the proper test for obviousness in this case is not whether the existence of rabeprazole sodium polymorphs is suggested by the prior art, but whether it would have been obvious to make the particular Form Z of rabeprazole sodium claimed in the instant application based on the prior art:

> The law of § 103 requires quite a different inquiry from that conducted by the ALJ. Thee correct inquiry is not whether the Bouzard monohydrate [polymorph] could have been produced by manipulation of other cefadroxil processes, once the existence of the Bouzard monohydrate was known.

> The question is whether it would have been obvious to make the Bouzard monohydrate, based on the prior art.

Bristol-Myers Co. v. U.S. Int'l Trade Comm'n, *supra* (emphasis added).

Here, the references cited by the Examiner suggest at most the possibility of additional rabeprazole sodium polymorphs. The Examiner has pointed to nothing in the cited references, however, that would suggest to one skilled in the art the particular Form Z claimed in the instant application, or a methods for its preparation. In fact, CEC, p. 32, cited by the Examiner, states that "no method yet exists to predict the polymorphs of a solid compound with significant certainty." The Examiner admitted as much by quoting the CEC passage under the enablement rejection at page 9 of the Final Office Action (discussed *infra*). Because of this uncertainty, Appellants submit that no *prima facie* case for obviousness of claims 1-3, 5-9, 26 and 27 under § 103(a) has been made out, and the rejection should not be sustained. *See Ex parte Andrews*, Appeal No. 2002-0941 of Application No. 09/166,445, now US 6,713,481 B1 (BPAI 2003) ("[T]he examiner has not adequately explained how a person having ordinary skill would have been led from 'here to there,' i.e., from the [prior art] compound having formula I to the crystalline polymorph form I recited in claims 1 through 5."); *Ex parte Portmann*, Appeal No. 2003-1199 of Application No. 09/125,328, now US 6,740,669 B1 (BPAI 2003) (same).

At page 5 of the Final Office Action, the Examiner stated in support of the § 103(a) rejection:

> [A]s . . . set forth by the court in In re Cofer 148 USPQ 268, Ex parte Hartop 139 USPQ 5252, that a product which is merely a different form of a known compound, notwithstanding that some desirable results are obtained therefrom, is unpatentable. The instant claims are drawn to the ***same pure substance*** as the prior art that only have *different arrangements and or different conformations of the molecule*. A mere difference in physical property is a well known conventional variation for the same pure substance is *prima facie* obvious. (Emphasis in original.)

As with the § 102 rejection, the Examiner again appears to be taking the position that new polymorphs are *per se* unpatentable over the originally

identified compound or previously identified polymorphs of the same compound. Such a rule, however, is inconsistent with the law on obviousness. *See Ex parte Andrews*, *supra* (quoting *In re Ochiai*, 71 F.3d 1565 (Fed. Cir. 1995) ("The use of *per se* rules flouts § 103 and the fundamental case law applying it. . . [R]eliance on *per se* rules of obviousness is legally incorrect and must cease."); *Ex parte Portmann*, *supra* (same). As discussed above, courts have consistently found new polymorphs to be patentable over other forms of the same compound.

The Examiner's reliance on *In re Cofer* and *Ex parte Hartop* are misplaced in this case. *In re Cofer* actually held the claimed crystalline 2,2-bis compound patentable because:

> [T]he board failed to address . . . whether the prior art suggests the particular structure or form of the compound or composition as well as suitable methods of obtaining the structure or form. (Emphasis added.)

354 F.2d 664, 668 (CCPA 1966). The *Cofer* court addressed the *Ex parte Hartop* decision, which had been relied upon by the board in finding the claimed crystalline 2,2-bis compound unpatentable:

> We think examination of the decisions relied on . . . in *Hartop* will demonstrate that the materials involved therein were found unpatentable where the alleged difference in form or purity of those substances was either disclosed or inherent therein. (Emphasis added.)

Id. at 667. Here, as discussed above, the references cited by the Examiner neither disclose or suggest the particular Form Z of rabeprazole sodium disclosed and claimed in the instant application.

The Board of Patent Appeals and Interferences has recently cautioned against the reliance on *Ex parte Hartop* in polymorph cases. As stated in *Ex parte Gala*:

> The examiner relies heavily on this proposition of law set forth in *Ex parte Hartop* . . . : "[m]erely changing the form, purity or another characteristic of an old product, the utility remaining the same as that for the old product, does not render the claimed product patentable." According to the examiner, polymorph form 2 loratadine is merely another form of an old product (polymorph form 1 loratadine) and

> both forms possess the same utility. Accordingly, the examiner concludes that applicants' claims, reciting polymorph form 2 loratadine, are unpatentable. We disagree. Here, we invite attention to *In re Cofer* . . . , where the court substantially discredited PTO reliance on the above-quoted proposition of law in *Hartop*. Like the situation presented in *Cofer*, the examiner in this case has not adequately established that the prior art (1) suggests the polymorph form 2 of loratadine; or (2) discloses or renders obvious a method for making the polymorph form 2 of loratadine. (Emphasis added.)

Appeal No. 2001-0987 of Application No. 09/169,109, now US 6,335,347 B1 (BPAI 2001); *see also Ex parte Andrews*, *supra* ("[T]he principal of law enunciated in *Ex parte Hartop* . . . has been substantially discredited in *In re Cofer* . . ."); *Ex parte Portmann*, supra (same).

According to the Examiner, Appellants do not point to any objective evidence which demonstrates that the claimed compound exhibits any properties which are actually different from the closest prior compounds. Appellants respectfully submit that such differences need not be demonstrated because a *prima facie* case of obviousness has not been made under the proper test described above. The CCPA in *In re Grose* specifically rejected the application of the law of structural obviousness, and hence a requirement for a showing of unexpected properties, when analyzing the patentability of new solid state forms:

> No reason exists for applying the law relating to structural obviousness of those compounds which are homologs or isomers of each other to this case. . . A zeolite, like those of the instant case, is not a compound which is a homolog or isomer of another, but is a mixture of various compounds related to each other by a particular crystal structure. Moreover, no other chemical theory has been cited as a basis for considering appellants' zeolite as prima facie obvious in view of [the prior art] zeolite R.

592 F.2d 1161, 1167-68 (CCPA 1979).

Accordingly, Appellants submit that claims 1-3, 5-9, 26 and 27 are not *per se* unpatentable under § 103(a), and the rejection should not be sustained.

C. Rejection of Claims 1-3, 5-9, 26 and 27 Under 35 U.S.C. § 112, First Paragraph

Claims 1-3, 5-9, 26 and 27 stand finally rejected under 35 U.S.C. § 112, first paragraph as allegedly failing to comply with the written description and enablement requirements. According to the Examiner, there is a lack of description as to whether the compound and compositions are able to maintain the crystalline form claimed. Similarly, according to the Examiner, the specification lacks direction or guidance for maintaining the compound and compositions in the crystalline forms claimed. The Examiner further states that there is no evidence that the instant form Z will not be identical to the prior art form because when crystalline solids are dissolved in solvent, all forms are amorphous.

Regarding written description, MPEP § 2163 states:

> An applicant shows possession of the claimed invention by describing the claimed invention with all its limitations. *Lockwood*, 107 F.3d at 1572, 41 USPQ2d at 1966. . . . Limitations may not, however, be imported into the claims from the specification. (Emphasis added.)

Regarding enablement, MPEP § 2164.08 states:

> All questions of enablement are evaluated against the claimed subject matter. The focus of the examination inquiry is whether everything within the scope of the claim is enabled. Accordingly, the first analytical step requires the examiner determine exactly what subject matter is encompassed by the claims. (Emphasis added.)

The subject matter of claims 1-3, 5-9, 26 and 27 is directed to crystalline Form Z of rabeprazole sodium, as well as compositions comprising the same. Contrary to the Examiner's position, the claims contain no limitation requiring that Form Z be maintained indefinitely, or that it be the only form present in the compositions, and Appellants submit that it is error to read such limitations into the claims. The instant specification at page 13, line 21 to page 17, line 21, as well as Examples 1-3, clearly describes and enables the preparation of Form Z of rabeprazole sodium and compositions comprising the same. Furthermore, one

of ordinary skill in the art would easily be able to determine the crystalline form(s) present in compounds and compositions before, during and after their preparation, such as by X-ray diffraction techniques (*see, e.g.*, the instant specification, page 9, line 12 to page 13, line 20), and thus determine whether a given material falls within the scope of claims 1-3, 5-9, 26 and 27.

Appellants further submit that reading the claims to encompass compounds and compositions where all crystalline structure of Form Z of rabeprazole sodium is lost (and hence its claimed solid state characteristics as well) is contrary to the plain meaning of the claim language. Claims 1-3, 5-9, 26 and 27 specifically recite "crystalline Form Z of rabeprazole sodium, having substantially the same X-ray powder diffraction pattern as shown in Figure 1." Accordingly, rabeprazole sodium in solution (and thus lacking any crystalline structure with the specified X-ray diffraction pattern) is outside the scope of the claims. Because the specification describes and enables the full scope of the claimed subject matter, Appellants submit that claims 1-3, 5-9, 26 and 27 are not invalid under § 112, first paragraph, and the rejection should not be sustained.

D. Rejection of Claims 1 and 6-9 Under 35 U.S.C. § 112, First Paragraph

Claims 1 and 6-9 stand finally rejected under 35 U.S.C. § 112, second paragraph as allegedly indefinite. According to the Examiner, the rejected claims recite the chemical name "rabeprazole," which the Examiner believes is a trade name. Citing *Ex parte Simpson*, 218 USPQ 1020 (BPAI 1982), the Examiner states that the use of a trade name renders the claim scope uncertain since it cannot be used properly to identify a particular material or product, only the source of the material or product. The Examiner believes that only the IUPAC name for rabeprazole will render the rejected claims definite.

Contrary to the Examiner's position, "rabeprazole" is not a trademark or trade name, but rather the name assigned by the U.S. Adopted Names ("USAN") Council, a cooperative effort among the American Medical Association ("AMA"), the U.S. Pharmacopeial ("USP") Convention and the American Pharmacists

Association ("APA"). Names selected by the USAN are normally used by the U.S. Food and Drug Administration ("FDA") as an official identifier for the compound, as noted in 21 C.F.R. § 299.4(e). As discussed in Appellants' previous response, rabeprazole sodium is shown in the electronic version of the FDA's "Orange Book" as the active ingredient in Eisai's product having the proprietary name "Aciphex®." Thus, rabeprazole sodium is a generic name which identifies its structure, and Aciphex® is a trademark which identifies its commercial source. *Cf.* Reddy, cited by the Examiner, which states that "[t]he chemical designation of Rabeprazole sodium is 2-[[[4-(3-methoxypropoxy)-3-methyl-2-pyridinyl]-methyl]sulfinyl]-1*H*-benzimidazole sodium." (Page 1, lines 7-8) (emphasis added.) The Examiner provided no support for the proposition that only an IUPAC name will suffice to render a claim definite. In fact, numerous U.S. patents have issued with claims reciting the term "rabeprazole." *See, e.g.*, U.S. Patent Nos. 6,926,907, 6,699,885, 6,552,048 and 6,174,902. Accordingly, Appellants submit claims 1 and 6-9 are not indefinite under § 112, second paragraph, and the rejection should not be sustained.

E. Rejection of Claims 1-3, 5-9, 26 and 27 for Obviousness-Type Double Patenting

Claims 1-3, 5-9, 26 and 27 stand provisionally rejected under the judicially created doctrine of obviousness-type double patenting as unpatentable over claims 1-13, 26 and 27 of copending U.S. Patent Application No. 10/786,556 in view of Haleblian, Muzaffar, Jain, C&E News, USP, Brittain and CEC. According to the Examiner, U.S. Patent Application No. 10/786,556 discloses crystal forms of the instant salts and corresponding compositions, and the ancillary references teach that mere existence of further polymorphs is not in itself regarded as unexpected.

According to MPEP § 804:

> A double patenting rejection of the obviousness-type is "analogous to [a failure to meet] the nonobviousness requirement of 35 U.S.C. 103" except that the patent principally underlying the double patenting rejection is not

> considered prior art. *In re Braithwaite*, 379 F.2d 594, 154 USPQ 29 (CCPA 1967). Therefore, any analysis employed in an obviousness-type double patenting rejection parallels the guidelines for analysis of a 35 U.S.C. 103 obviousness determination. *In re Braat*, 937 F.2d 589, 19 USPQ2d 1289 (Fed. Cir. 1991); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985).

Appellants note that U.S. Patent Application No. 10/786,556 is the instant application. For purposes of this appeal, Appellants assume that the Examiner meant the basis for the rejection to be the pending claims of copending U.S. Patent Application No. 10/505,826 ("the '826 application"). The claims of the '826 application are directed to crystalline Forms X and Y of rabeprazole sodium having an X-ray powder diffraction pattern substantially different from that of the instantly claimed Form Z. As with the obviousness rejection discussed above, the Examiner pointed to nothing in the claims of the '826 application or the cited ancillary references that would suggest to one skilled in the art the particular Form Z of rabeprazole sodium claimed in the instant application, or a method for its preparation.

Accordingly, Appellants submit that claims 1-3, 5-9, 26 and 27 are not invalid for obviousness-type double patenting, and the rejection should not be sustained. *See Ex parte Andrews*, *supra* ("As discussed above, the examiner has pointed to nothing in either claims or the disclosure of the [commonly assigned] patent that would have suggested the S and T crystal forms of delavirdine mesylate to a person of ordinary skill in the art. We therefore reverse the rejection for obviousness-type double patenting."); *Ex parte Portmann*, *supra* ("The claims of the issued patent recite crystal modifications B and C of [the compound], which are patentably distinct from crystal modifications A and A' recited in the claims before us.").

CONCLUSION

Appellants submit that claims 1-3, 5-9, 26 and 27 meet the requirements for patentability under §§ 102, 103 and 112. Accordingly, reversal of the Examiner's rejections is appropriate and is respectfully solicited.

Respectfully submitted,

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CLAIMS APPENDIX

1. A compound which is a crystalline Form Z of rabeprazole sodium, having substantially the same X-ray diffraction pattern as shown in Figure 1.

2. The compound of claim 1 having an X-ray diffraction pattern, expressed in terms of 2 theta angles, that includes four or more peaks selected from the group consisting of 4.69 ±0.09, 9.07±0.09, 9.42±0.09, 11.25±0.09, 14.71±0.09, 16.24±0.09, 17.26±0.09, 18.52±0.09, 19.32±0.09, 19.63±0.09, 19.92±0.09, 20.80±0.09, 21.48+0.09, 23.07±0.09, 24.81±0.09, 25.70±0.09, 27.47±0.09, 30.01±0.09, 30.65±0.09, 33.37±0.09, and 36.95±0.09.

3. The compound of claim 2 having an X-ray diffraction pattern expressed in terms of 2 theta angles and obtained with a diffractometer equipped with a Cu K alpha-1 radiation source, wherein said X-ray powder diffraction pattern includes five or more peaks selected from the group consisting of peaks with 2 theta angles of about 4.694, 9.070, 9.417, 11.254, 14.712, 16.241, 17.264, 18.522, 18.522, 19.320, 19.626, 19.920, 20.802, 21.477, 23.073, 24.814, 25.702, 27.470, 30.009, 30.653, 33.365, and 36.950.

5. The compound of claim 1, which has an endo-exo pattern with identified peaks of about 106.5°C and 228.8°C in its differential scanning calorimetry thermogram.

6. Rabeprazole sodium as a solid, wherein at least 80 % by weight of said solid rabeprazole sodium is a crystalline Form Z of rabeprazole sodium, having substantially the same X-ray diffraction pattern as shown in Figure 1.

7. Rabeprazole sodium of claim 6, wherein at least 90 % by weight of said solid rabeprazole sodium is the crystalline Form Z.

8. Rabeprazole sodium of claim 6, wherein at least 95 % by weight of said solid rabeprazole sodium is the crystalline Form Z.

9. Rabeprazole sodium of claim 6, wherein at least 99 % by weight of said solid rabeprazole sodium is the crystalline Form Z.

26. The compound of claim 1, having substantially the same differential scanning calorimetry curve as shown in Figure 2.

27. The compound of claim 1, having a melting point about 224-230°C.

EVIDENCE APPENDIX

None.

RELATED PROCEEDINGS APPENDIX

None.